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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,316	07/18/2003	Cheng Shu Chaw	6565-66400	4339

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/622,316	CHAW ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *9 and 20-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *18 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/07/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I claims 1-14 in the reply filed on 01/04/2007 is acknowledged. The traversal is on the ground(s) that Groups I and II are both related products. This is found persuasive because both groups I and II require the same microparticles and would require minimal if any additional searching. Therefore the examiner has rejoined groups I and II and will examine claims 1-9 and 11-19 as suggested by applicants. Claim 10 is withdrawn for being directed to a non-elected species. The restriction between groups I-II with group III, the method to prepare a sustained release formulation, is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 12 is objected to because of the following informalities: "14 000" and "42 000" are missing commas, the numbers should read "14,000 to 42,000". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically there is no support in the specification that the polymer concentration is about 2% to 6% w/v of the microparticle. The only support the examiner could find was the polymer was added to a solvent mixture in a concentration range of 2-6% w/v but this is not the final concentration of polymer in the microparticle because the mixture is then spray dried which would obviously increase the amount w/v of the polymer in the microparticle since the solvent is evaporated. See [0038] in USPUB 2005/0013869. It is suggested by the examiner that applicants either cancel claim 13 or amend the claim to include a product by process type of limitation in which the polymer is added to a solvent mixture in the claimed concentration range.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8,10-13,15-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Roorda et al. (US5,543,156).

Roorda teaches bioerodable devices comprised of a) bioerodable polymer such PGLA (including a 50:50 mixture of lactic and glycolic acids, MW 30,000),

poly(orthoesters), polyesters, polyanhydrides and mixtures and combinations of the above polymers b) an active agent including scopolamine (a known anti-cholinergic agent) in combination with eserine salicylate (same as physotigmine). See abstract, col 4 lin 7-12, col 6 lin 60-63, examples and claims 1-2. The devices could be manufactured by standard techniques to form microparticles and the devices could be placed on or in the wounds of an animal by injecting the microparticles. See col 7 lin 31-59. Regarding claim 18 from the figures and examples several of the compositions of Roorda were releasing the active after one week, thus the limitation is met. Furthermore even if the compositions disclosed as having the release rates did not contain all of applicants claimed ingredients, such as the active, it is still inherent that since Roorda teaches the exact same microparticle composition as claimed by applicants the release rate will be the same. Applicants are apparently claiming a new use or function or perhaps an unknown property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1-8 and 10-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Gao et al. (US 2003/0118649 A1).

Gao teaches drug delivery devices comprised of a core comprising a bioactive agent and a biodegradable polymer selected from PLGA, at all lactide to glycolide ratios, polyester, polyorthoester and polyanhydride and a first layer disposed around the central core comprising a second bioactive agent and a biodegradable polymer such as PLGA and poly(vinyl acetate), the MW of the above polymers could be between 10 kD to 500 kD. See abstract, [0016],[0020],[0078],[0081],[0089], [0093],[0108] and claims. The drug delivery device could come in the form or a microsphere/microparticle and could be administered by injection. See [0044],[0045],[0050],[0075] and [0078]. The device can contain one or more bioactive agents that can be selected from eserine salicylate and scopolamine in concentrations of the first layer from 0.1 to 60%. See [0017] and [0100]. Regarding claim 18 from the figures and examples several of the compositions of Gao were releasing the active after one week, thus the limitation is met. Furthermore even if the compositions disclosed as having the release rates did not contain all of applicants claimed ingredients, such as the active, it is still inherent that since Gao teaches the exact same microparticle composition as claimed by applicants the release rate will be the same. Applicants are apparently claiming a new use or function or perhaps an unknown property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does

not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-9 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al. (US5,543,156). Roorda is disclosed above. Roorda discloses all of applicants claimed invention but is silent on the specific amount of physotigmine. However, Roorda discloses that the amount of active agent employed in the delivery device will be that amount necessary to deliver a therapeutically effective amount of the agent to achieve the desired result at the site of application. In practice, this will vary

depending upon the particular agent, the severity of the condition, and the desired effect, as well as the desired rate and duration of release. Thus the skilled artisan would see from the disclosure of Roorda that the amounts of the therapeutic would vary and the most advantageous amount of active contained in the delivery device would be obtained through normal routine experimentation. It also would be obvious to use the amounts of active that were disclosed in the experimental sections of Roorda. In the experimental section the drug loading concentration was 5 and 10% by weight, thus the skilled artisan could see that since the bioactive physotigmine is listed as being useful in the composition to use a microparticle formulation containing 10% physotigmine would have been very obvious. Besides the above arguments generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

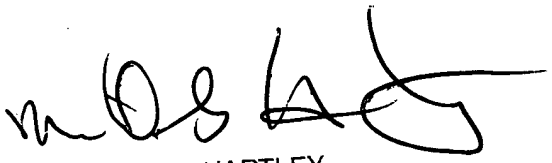
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER